Suggestions for Organizing Information for a CCOP Research Base Application

In preparing a CCOP Research Base application, you must follow the instructions provided in the **RFA CA-07-025** (*Community Clinical Oncology Program*) and the *Application for a Public Health Service Grant* (PHS-398) (Rev.9/2004, Interim Revision 04/2006) available at: http://grants.nih.gov/grants/forms.htm and its accompanying packet of forms.

NOTE: This edition of the PHS 398 is organized into three distinct parts, each of which is available as a separate file in MS Word and PDF versions. Applicants will need to use all three parts of the instructions to prepare a complete and acceptable application.

The PHS 398 instructions include:

Part I: Instructions for Preparing the Application
Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan
Part III: Policies, Assurances, Definitions and Other Information

The suggestions and sample tables provided in this Suggestions for Organizing Information for a CCOP Research Base Application are provided as a supplement to the PHS-398 (Rev.9/2004, Interim Revision 04/2006), NOT A REPLACEMENT. While, these suggestions and tables are not mandatory, they may help the applicant supply all the information required by the RFA while remaining within the page limitations (see **RFA-CA-07-025**, Part II, Section IV.2. Content and Form of Application Submission).Following this suggested format may assist reviewers in their evaluation of the application=s resources and capabilities. The tables provided in this format may be included in the application as part of the Resources, Progress Report and Human Subject Research sections, as appropriate.

NOTE**: Requirement of DUNS Numbers on NIH Applications** - Use of the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is required when applying for Federal grants or cooperative agreements. See NIH Guide Notice dated August 14, 2003 and the DUNS Q&A (MS Word) document for more information.

NOTE: **Other Support** should NOT be submitted with the application. If this information is included in the application, the application may be returned to the applicant organization WITHOUT peer review. See PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part III** (*Policies, Assurances, Definitions, and Other Information*), G. **Just-in-Time Policy**, pages 8-9. Do NOT confuse "**Research Support**" with "**Other Support**." Although they sound similar, these parts of the application are very different. See **Part III (***Policies, Assurances, Definitions, and Other Information)* page 9.

GENERAL INSTRUCTIONS

Although formatting and submission information is provided in the PHS-398 (Rev.09/2004 Interim Revision 04/2006), some of the requirements are repeated in these instructions to emphasize the importance of some sections of the application**.** Please refer to the **RFA CA-07-025** and the PHS-398 (Rev.09/2004 Interim Revision 04/2006) **Part I, II and III** for complete instructions.

X Prepare the application using the PHS 398 MS WORD or PDF *form* pages and *format* pages as provided. *Form* pages must be identical to those provided in the PHS 398. You may substitute computer generated facsimiles for government-provided forms; however they must maintain the exact wording and format of government forms, including all captions and spacing. *Format* pages are intended to assist you in the development of specific sections of the application. Alternatively, you

may create a page similar to any format provided as long as all the requisite information is included.

Font sizes on some PHS 398 form pages vary due to field or space limitations. The PHS 398 MS WORD and PDF *Form* Pages as provided are acceptable to NIH. All other sections of the application (e.g., Biographical Sketch; Literature Citations; and the Research Plan) must conform to the font and format requirements as stated in the PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*), **Format Specifications**, on pages 17-18.

- Include all pertinent information in the text and tables. **DO NOT** use the Appendix for any material that all reviewers need to see because, this information will not be reproduced for all the reviewers. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*), **Appendix**, page 41 for more details.

- **Do not** include photographs or other materials that are not printed directly on the application page in the body of the application. Pictures or materials that are glued or taped onto the application pages are incompatible with the current duplication/scanning process. You may include black-and-white or color images in the six (6) submitted copies provided such images are printed directly on the application page and are critical to the content of the application.

  Do not submit oversized documents, materials that do not reproduce well or institutional public relations-type documents.

- Include a table of contents (see Form Page 3), so that reviewers can identify each part of the application by page number. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** *(Instructions*), 3. **Research Grant Table of Contents**, page 28. NOTE: Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

CCOP Research Base APPLICATION DUE DATE

- Submit the applications **by August 28, 2006**.

- Affix RFA label to bottom of face page. See the Mailing Address and RFA Label Form.

- Late applications will not be accepted. Receipt dates listed in PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*) **Application Submission Dates**, Table 2 on pages 46-47 **DO NOT apply** to applications responding to **RFA-CA-07-025**. The application deadline is referenced in the RFA.

REVISED/RESUBMISSION (AMENDED) APPLICATIONS

An unsuccessful applicant from the previous year=s competition is a *revised/resubmission (amended)* application that **MUST** include an Introduction of **not more than three pages** that summarize the substantial additions, deletions and changes to the application. The Introduction must also include responses to the criticisms and issues raised in the summary statement. NIH allows the submission of up to two revised applications but no longer restricts those submissions to a two-year timeframe. See PHS-398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*), **Revised/Resubmission Applications**, page 19, (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-041.html).

RENEWAL APPLICATIONS

An application from a currently funded CCOP Research Base is a ***renewal*** (*competing continuation*) and must include a progress report. See PHS-398 (Rev.09/2004 Interim Revision 04/2006) **Part I**

(*Instructions*), C. **Preliminary Studies/Progress Report**, page 35.

The progress report, at a minimum, should include:

- Summary of CCOP Research Base activities and accomplishments over the funding period, with a clear presentation of yearly accrual (separately for treatment and cancer prevention/control) from affiliated CCOPs;

- Progress in implementing NCI approved cancer prevention/control clinical trials;

- Complete description of how the applicant has met the special cooperative agreement terms and conditions of the award;

- Clear presentation of annual accrual to each NCI approved prevention/control clinical trials for CCOPs and CCOP Research Base members and affiliates;

- Report and table on the enrollment of women/men and on ethnicity/race of research participants during the previous funding period (see PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*), page 19, C. **What Inclusion/Enrollment Table Should Principal Investigators Use for Reporting Accrual Data to NIH (New versus Old Table);**

- Status of prevention/control clinical trials under development (i.e. Concepts and Protocols – see definition of these documents on Table 3 and 4);

- If a **renewal** application has currently funded "prevention member(s), the application must include a progress report addressing how the member(s) have contributed to the goals of the CCOP Research Base in relation to cancer prevention research. Include data on accruals to chemoprevention trials lead by the CCOP Research Base applicant, if applicable. Describe contributions to the following areas that apply: pre-clinical studies on the path to chemoprevention protocol(s); chemoprevention protocol(s) development; ancillary studies to prevention trials; other research activities that contribute to the CCOP Research Base's cancer prevention program.

- CCOP Research Base applications that include funding for an ongoing large-scale prevention trial(s) (e.g., Study of Tamoxifen and Raloxifene, (STAR)) should include a progress report that outlines the major milestones for the trial(s) during the funding period (i.e., three to five years).

NEW APPLICATIONS

New applications are advised to complete all of the attached Sample Tables. Although the tables are not required, they may help the reviewers in their evaluation of the application. Since new applicants have not worked with CCOPs in the past year, they may provide information on treatment accruals from their members and affiliates as an indication of their potential for future CCOP treatment accruals. See **Sample Table 1.** Likewise, new applications may present information regarding cancer

prevention and control clinical trials even though these are not NCI approved. See **Sample Tables 2, 3, and 4**.

SPECIFIC INSTRUCTIONS

The following suggestions are provided to assist the applicant in addressing PHS 398 (Rev.09/2004 Interim Revision 04/2006) **Part I** (*Instructions*) **Preparing Your Application**, C. 6.RESOURCES (pages 33-34) and C.7.E. HUMAN SUBJECTS RESEARCH (pages 36-37). The suggestions are listed in the same sequence as the instructions in the PHS-398.

RESOURCES

Use the Resources Format Page (or create pages similar to the format page with the requisite information). See PHS-398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*) **Preparing Your Application**, C. 6.RESOURCES (pages 33-34) and integrate the following format suggestions to describe Resources.

Type of Research Base

Indicate organizational type and research focus of the application:

- NCI Clinical Cooperative Group (NCI-funded) **for cancer treatment *and* prevention and control clinical trials;**
- NCI-designated Cancer Center (NCI-funded) for **cancer treatment *and* prevention and control clinical trials;**
- NCI-designated Cancer Center (NCI-funded) for *only* **cancer prevention and control clinical trials.**

Organization of CCOP Research Base

- Describe the organizational structure of the CCOP Research Base. If there is more than one functional unit (e.g., administrative, operations, statistical), indicate the leadership in each.
- Describe the stability of the functional unit within the organizational structure, as well as the relationship and integration of the functional unit with other functional units in the CCOP Research Base.
- Provide an organizational chart showing the relationship(s) between scientific and administrative units, vis-a-vis the conduct of cancer treatment and/or prevention/control clinical trials.
- Describe the relationship of the CCOP Research Base to any other parent organization (e.g., fiscal agent).

$ Suggested page limit – 2 pages.

RESEARCH PLAN

There is no specific Form Page for the Research Plan. The research plan should include sufficient information needed for evaluation of the project. Follow the instructions provided in PHS-398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*) Research Plan (pages 34-36) and integrate the following format suggestions to describe the research plan.

Preliminary Studies/Progress Report

- **Past Experience**

  < If applicable, describe experience in conducting multi-institutional cancer treatment and prevention/control clinical trials during the last 5 years (or applicable project period).

  < Suggested page limit – 3 pages.

Research Design and Methods

- If applicable, describe the relationship of the CCOP Research Base to investigators and institutions (e.g., CCOPs, cooperative group affiliate programs, member institutions and affiliates) contributing to clinical trials.

- Describe the relationship of physician investigators to main member institutions and affiliate institutions.

- Describe the proposed relationship to CCOPs. Include how the CCOPs will be integrated into the activities and decision-making processes of the CCOP Research Base organization. Address the CCOP's scientific and administrative contributions to the Research Base organization.

- Suggested page limit – 4 pages.

Proposed Development and Implementation

- Outline the organizational process for development and implementation of cancer prevention and control clinical trials.

- Suggested page limit – 3 pages.

Cancer Prevention and Control Research

- Describe the organizational structure for conducting cancer prevention and control research. Indicate responsibilities of the cancer control committee (or its equivalent) to the CCOP Research Base, and the role of the CCOPs, cooperative group affiliate programs, group members, and other affiliates on the committee. Indicate the relationship of the cancer control

committee (or its equivalent) to disease site and modality committees.

- State the broad, long-term objectives of the cancer prevention and control research program.

- Provide the scientific rationale for the proposed cancer prevention and control clinical trials. Specifically identify the gaps that the research is intended to fill. Outline the methodology to be used to accomplish the specific aims of the research. Discuss the process by which priorities in cancer prevention and control research are identified, developed, and implemented within the CCOP Research Base.

- Describe in detail at least two examples of cancer prevention and control clinical trials, including underlying hypotheses, study design, and implementation plan.

- If applicable, include proposals for specific non-CCOP member institutions for consideration as "prevention members." Use **Table 7** to list the prevention members included in the application. Refer to the RFA for further details on the information to address in the application for "prevention member(s)."

Quality Control and Monitoring

- Describe procedures for ensuring and assessing patient eligibility and availability. Describe eligibility checks, registration, and quality control procedures for all data (e.g., medical oncology, surgery, pathology, radiation therapy, cancer prevention and control studies).

- Describe methods of on-site auditing or monitoring for data verification and assurance of compliance with regulations for the protection of human subjects (IRB approval and informed consent) and for investigational drug accountability.

- Describe mechanisms for periodic review of performance (qualitative and quantitative) by the CCOP Research Base and criteria for continued affiliations. If mechanisms are different for cancer treatment and prevention/control, describe these differences.

- Include a budget for auditing and quality control activities with complete justification for each budget item.

- Provide a list of Institutions and their audit schedule using **Sample Table 8** (see directions for which institutions to include on the sample table) for large-scale prevention trials (e.g., the Selenium and Vitamin E in Prostate Cancer Trial (SELECT)); and/or other prevention trials that involve institutions which are NOT an NCI Clinical Cooperative Group treatment trial institution.

TABLES SUMMARIZING PROTOCOL ACTIVITY AND CLINICAL SITES

To assist the applicant in providing material sufficient to permit adequate review of study activity and study sites while maintaining clarity and brevity, we have included the following sample tables as suggested formats for providing specific information.

NOTE: With respect to the PHS 398 page limitation, each of the Tables 1 through 8 counts as **one**

page, even though an applicant may include multiple pages for one or more of these Tables (e.g. 8 pages of Table 1 will count as 1 page against the page limitation referenced in the RFA-CA-07-025).

Protocol Activity Tables

Sample Table 1 -	Accrual to NCI Approved Cancer Treatment Trials available for use by CCOP
Sample Table 2a -	Accrual to NCI Approved Cancer Prevention and Control Trials conducted by your Research Base for use by CCOP and your members/affiliates, and other Research Base members/affiliates (if for Inter-group Studies)
Sample Table 2b -	Accrual to Inter-group NCI Approved Cancer Prevention and Control Trials sponsored by other Research Bases for use by your members/ affiliates
Sample Table 3 -	Cancer Prevention and Control Concepts Approved by NCI for Protocol Development
Sample Table 4 -	Cancer Prevention and Control Concepts under Development

Clinical Site Tables

Sample Table 5 -	CCOP Affiliations
Sample Table 6 -	Member/affiliate participation in Cancer Prevention and Control
Sample Table 7 -	APrevention Members@
Sample Table 8 -	Institution audit schedule for Prevention Trials, large-scale and other

Human Subjects Research

- Create a section entitled "**Human Subjects Research**" immediately following the last entry in the Research Design and Methods section.

  < Instructions for the Human Subjects Research section are in the PHS 398 (Rev. 09/2004, Interim Revision 04/2006), **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*).

  As the first entry create a heading entitled "***Protection of Human Subjects***." See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part II**, (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages13-15 for the elements that should be addressed under this heading.

  < Address the involvement of human subjects and protection from research risks relating to their participation in the proposed research plan, Applicants should refer to the PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part I** (*Instructions*), **Decision Table** on page 38 to determine the relevant scenario that applies to their application. The majority, if not all, CCOP Research Base applications will need to address the topics outlined under Scenario F.

  Create a heading entitled "***Data and Safety Monitoring Plan***."

< Describe the CCOP Research Base's data safety and monitoring plan(s) for clinical trials. For applications involving both cancer treatment and prevention/control clinical trials, specify differences in the data and safety monitoring plan(s) for treatment and prevention/control trials, if such differences exist. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006) **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages 14-15 for more information on the elements of data safety and monitoring that should be addressed in the application.

In addition, the NCI has developed a document: Data and Safety Monitoring Guidelines: A guide to the formulation of DSM plans for all phases of cancer clinical trials, in accordance with NIH requirements that is available at: http://www.cancer.gov/clinical_trials

(NOTE: A detailed Data Safety and Monitoring Plan must be submitted to the applicant's Institutional Review Board and subsequently to the funding Institute and Center for approval prior to accrual of human subjects.)

< A Cancer Center CCOP Research Base, may include the NCI-designated Cancer Center's approved institutional plan in the human subjects section of the application and describe how the CCOP Research Base's studies are integrated into the Cancer Center's plan. Cancer Center CCOP Research Base involved in treatment and cancer prevention/control trials should specify differences, if these exist, in monitoring plans for treatment trials versus prevention/control trials.

Inclusion of Women and Minorities

- Create a section heading entitled "***Inclusion of Women and Minorities***," and place it immediately following the "Protection of Human Subjects" section. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006), **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages 16-20. Note the additional information to be provided for applications that involve NIH-defined phase III clinical trials on page 17.

Inclusion of Children

Create a section entitled "***Inclusion of Children***." This section should immediately follow the last entry in Inclusion of Women and Minorities section.

< For applications that include a pediatric component, the plan for including children should be described. See **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) pages 21-22 for additional guidance on information to include in your description.

< If children will be excluded from the research, the application must present an acceptable justification for the exclusion. For the applications that do not include a pediatric component see **Part II** (*Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*) Justifications for Exclusion of Children on pages 21-22 (see 4.b.).

Resource Sharing

(1) Data Sharing Plan

All applications must address their data-sharing plan in their application. Data sharing pertains to both published and unpublished but **complete data sets**. Investigators should refer to http://grants.nih.gov/grants/policy/data_sharing/) for guidance on addressing this application requirement. See PHS 398 (Rev. 09/2004, Interim Revision 04/2006)) **Part I** (*Instructions*), Resource Sharing, page 41.